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Phenol and Salt

Interim Registration Review Decision
Case Number 4074

August 2020

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I. INTRODUCTION

This document is the Environmental Protection Agency's (the EPA or the agency) Interim Registration Review Decision (ID) for phenol and salt (PC Code 064001 and 064002, case 4074), and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. Additional information on phenol and salt can be found in the EPA's public docket (EPA-HQ-OPP-2012-0810) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www.epa.gov/pesticide-reevaluation. In 2006, the agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA is issuing an Interim Decision for phenol and salt so that it can move forward with aspects of the registration review that are complete. The agency has evaluated risks to listed species and is making a "no effect" finding for listed species and designated critical habitat and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required. The agency will complete endocrine screening for phenol and salt, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) 408(p), before completing this registration review. See the *Phenol and Salt Proposed Interim Registration Review Decision* appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the phenol and salt registration review.[1]

[1] *Phenol and Salt Proposed Interim Registration Review Decision*, https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0810-0010

The phenol and salt case contains two active ingredients: phenol and the alkali metal salt of phenol - sodium phenate. There are three registered products that contain phenol as an active ingredient (a.i.), two of which also contain sodium phenate as an active ingredient. Phenol and salt have bactericidal, virucidal, fungicidal, mildewcidal, and tuberculocidal properties and eliminate odor. Products containing phenol and sodium phenate are registered for use as hard surface disinfectants, deodorizers and cleaners, and are primarily used in remediation situations such as mold/mildew cleaning and crime scene clean-up. They are also registered for use in food handling/storage premises and hospitals, as well as in residential areas and to clean and deodorize washable fabrics.

This document is organized in five sections: the *Introduction*, which includes this summary and a summary of public comments and the EPA's responses; *Use and Usage*, which describes how and why phenol and salt is used and summarizes data on its use; *Scientific Assessments*, which summarizes the EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; the *Interim Registration Review Decision*, which describes the mitigation measures required to address risks of concern and the regulatory rationale for the EPA's ID; and, lastly, the *Next Steps and Timeline* for completion of this registration review.

A. Summary of Phenol and Salt Registration Review

Pursuant to 40 CFR § 155.50, the EPA formally initiated registration review for phenol and salt with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of phenol and salt, which is available in the public docket at regulations.gov under docket ID EPA-HQ-OPP-2012-0810.[2]

- December 2012 - The *Phenol and Salt Preliminary Work Plan* (PWP*)* was posted to the docket for a 60-day public comment period.

- May 2013 - The *Phenol and Salt Final Work Plan* (FWP) was issued.

- April 2016 – GDCI-064001-1587 - A Generic Data Call-In (GDCI) for phenol was issued for data needed to conduct the registration review risk assessments. All data were submitted and the GDCI was satisfied.

- April 2016 – GDCI-064002-1588 - A Generic Data Call-In (GDCI) for sodium phenate was issued for data needed to conduct the registration review risk assessments. All data were submitted and the GDCI was satisfied.

- November 2019 - The agency announced the availability of the *Registration Review Draft Risk Assessment for Phenol and Salts* (DRA) for a 60-day public comment period. One comment was received from an anonymous commenter concerning the risks that

[2] https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0810

were identified in the DRA. The comment did not change the risk assessments or registration review timeline for phenol and salt.

- May 2020 - The agency completed the *Phenol and Salt Proposed Interim Registration Review Decision* (PID) and announced its availability in the Federal Register in the docket for a 60-day public comment period. No comments were received.

- August 2020 – The agency has completed the *Phenol and Salt Interim Registration Review Decision* and will announce its availability in the Federal Register.

B. Summary of Public Comments on the Proposed Interim Decision and Agency Responses

During the 60-day public comment period on the *Phenol and Salt Proposed Interim Registration Review Decision*, which opened May 5, 2019 and closed on July 6, 2020, the agency received no comments concerning the phenol and salt PID.

II. USE AND USAGE

Phenol and its alkali metal salt - sodium phenate - have bactericidal, virucidal, fungicidal, mildewcidal, and tuberculocidal properties and eliminate odor. Products containing phenol and salt are registered for use as hard surface disinfectants, deodorizers and cleaners and are primarily used in remediation situations and hospital cleaning. In the hospital setting, phenol products are meant to be used as part of a regular cleaning routine. Mopping, trigger spray bottles and ready-to-use wipes are all used in these sites. These products are also registered for residential uses, where trigger spray bottles and wipes would be favored.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the agency's human health risk assessment was presented in the PID. No risks of concern were identified in the assessment for residential handlers, aggregate exposure or cumulative exposure. The agency identified dietary risks of concern as well as risks for occupational handlers of phenol products. Dietary risks of concern were identified for all population subgroups resulting from the use of phenol and salt products as hard surface cleaners in residential and commercial settings. Occupational dermal and inhalation risks of concern are anticipated to result from the use of phenol and salt products by hospital cleaning staff.

Since the PID, there have been no changes to the agency's previous human health risk conclusions. For additional details on the human health assessment for phenol and salt, see the

Registration Review Draft Risk Assessment for Phenol and Salts, which is available in the public docket at regulations.gov under docket ID EPA-HQ-OPP-2012-0810.[3]

1. Human Incidents

A search of the agency's Incident Data System (IDS) as of July 17, 2020 did not identify any major human health incidents that involved phenol or sodium phenate. The agency will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern.

2. Tolerances

There are two tolerance exemptions established for phenol as an inert ingredient (solvent/co-solvent) in pesticide products used on growing crops (40 CFR 180.920) and on livestock (40 CFR 180.930). At the time of the RED, there were no active registrations for those uses; therefore, the document recommended the tolerance be revoked. Since the RED, phenol has again been added as an inert ingredient and is currently in pesticide products used on livestock, and the tolerances continue to be within the CFR. However, there continue to be no registrations for products containing phenol as an inert ingredient for the 40 CFR 180.920 use, and EPA is recommending in this document that the tolerance exemption for that use be revoked.

Various phenol and salt products contain use sites that fall under 40 CFR 180.940(a), which include residues found on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. No tolerance is currently established within the CFR for these uses. However, due to the dietary risks identified above, the agency is proposing that the food-contact surface use patterns no longer be permitted (See Section IV. A. 1.).

3. Human Health Data Needs

The agency has determined that the toxicological database for phenol and salt is complete and data is not needed at this time.

B. Ecological Risks

The agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of phenol and salt. For additional details on the ecological assessment for phenol and salt, see the *Registration Review Draft Risk Assessment for Phenol and Salts*, which is available in the public docket at regulations.gov under docket ID EPA-HQ-OPP-2012-0810.

1. Risk Summary and Characterization

[3] https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0810-0007

A summary of the agency's ecological risk assessment was presented in the PID. Due to the low exposure potential from the registered uses, the rapid degradation through multiple pathways in environmental media, and moderate to low toxicity to non-target aquatic organisms - both terrestrial and aquatic (including aquatic plants) - risks are not expected. Therefore, the use of this chemical will not cause adverse effects to non-target organisms, including honey bees. The EPA is making a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required for the current uses of phenol and salts in antimicrobial products.

Since the PID, there have been no changes to the agency's previous ecological risk conclusions. For additional details on the ecological assessment for phenol and salt, see the *Registration Review Draft Risk Assessment for Phenol and Salts*, which is available in the public docket at regulations.gov under docket ID EPA-HQ-OPP-2012-0810.[4]

2. Ecological Incidents

A search of the Incident Data System (IDS) on July 17, 2020 returned one ecological incident involving phenol or sodium phenate. The incident occurred in 2015 and involved the deformation of 60 acres of avocados after direct application. It did not involve any currently registered pesticidal use of phenols.

The agency will continue to monitor ecological incident information as it is reported to the agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

There are no ecological or environmental fate data gaps and there are is no additional data required at this time.

C. Benefits Assessment

Phenol and its salt, sodium phenate are used as hard surface disinfectants in a wide variety of locations. The primary use sites for phenol are hospitals and for remediation such as mold/mildew cleanup, crime scenes, etc. Phenol has been used as a disinfectant since the late 1800s. It is easily manufactured in large quantities; thus, it is inexpensive to utilize in cleaning products.

According to information that a registrant provided via personal communication, phenol occupies a small share of the hospital disinfectant market, and it has been shown to be an effective addition to a regular cleaning regimen in hospitals.[5] It does not replace other common

[4] https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0810-0007
[5] Email communication with Jarett Lezdey from World Pharm-Trust. December 17, 2019

disinfectants on the market, such as iodine and iodophors, quats, glutaraldehyde, o-phenylphenol (OPP), p-Chloro-m-cresol (PCMC), peroxy compounds, peracetic acid and others[6] because it has a slower kill time than many competitors' products.

Additionally, registrants have indicated that unlike several other disinfectants, phenol and salt is stable after being sterilized by gamma irradiation. The use of sterile disinfectants is required in some settings such as cleanroom environments, making phenol and salt a valuable option for this use.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

In the Registration Review Draft Risk Assessment that was completed for phenol and salt, human health risks were identified for the dietary route of exposure from commercial uses, the occupational dermal, and the occupational vapor inhalation routes of exposure. The agency has actively engaged with both registrants for the required mitigation measures to address the risks of concern. These mitigation strategies include revising labels to limit uses to non-food contact surfaces, as well as limiting use frequency and/or requiring the use of personal protective equipment (PPE) for occupational uses.

No mitigation is required at this time for ecological exposures. Due to the low exposure potential from the registered uses, the rapid degradation through multiple pathways in environmental media, and moderate to low toxicity to non-target organisms - both terrestrial and aquatic (including aquatic plants) - risks are not expected.

1. Mitigation Measures for Commercial Dietary Uses of Phenol and Salt

To mitigate the chronic commercial dietary risks of concern, the agency is requiring that registrants alter the label language of their products to restrict use on food contact surfaces. The agency has contacted the registrants, and they have agreed to make these label changes. The products may continue to be used in commercial kitchens and food processing areas; however, the label language must be revised to clearly state that the product must only be used on floors and walls, in addition to specifying that the products are not intended for use on food contact surfaces. See Appendix B for details. Additionally, once the food uses are removed from the labels, a tolerance or an exemption will not be required.

2. Mitigation Measures for Dermal Risks of Concern from Mopping for Occupational Handlers

A comment submitted to the docket for the DRA by the registrant Contec, Inc. provided information that the average daily amount of phenol product used in a hospital would be roughly 1.5 gallons – significantly less than the DRA assumption of 58 gallons per day. This estimate

[6] *Specialty Biocides Regional Market 2012-United States.* 2013. Kline & Company.

was based on yearly sales of the registered product to hospitals. Therefore, the dermal exposure is expected to be much less than originally assumed, and risks would not be expected for the hospital mopping use of phenol products.

The commentor further stated that the largest and second largest consumers purchase 24,048 gal/year (65 gal/day) and 14,176 gal/year (38.8 gal/day) for non-healthcare and industrial uses, respectively. The risks associated with these non-healthcare/industrial uses would be similar to those outlined for hospital workers modeled in the DRA, and are of concern. To ensure that the workers in the non-healthcare/industrial fields are protected, dermal PPE is required to mitigate the risk of concern.

Therefore, to address the risk identified for the dermal exposure resulting from the mopping uses, the agency is requiring that occupational handlers use chemical-resistant gloves while mopping with phenol and salt products. The agency will require gloves statements that are consistent with Chapter 10 of the Label Review Manual and list the appropriate chemical resistant glove types to use.[7] Chemical-resistant gloves reduce the possibility of dermal contact with phenol products and would bring the MOE above the target of 100, which is the level of concern. Registrants are in agreement with this mitigation strategy, which includes labeling changes. See Appendix B for details.

3. Mitigation Measures for Vapor Inhalation Risks of Concern for Occupational Handlers

In order to address the vapor inhalation risks identified for occupational handlers, two mitigation strategies are being required.

(1) *Reduction in Duration of Product Use*

The DRA comment received by the agency indicated that exposure in specialty hospital areas (not patient rooms) is greatly decreased compared to the general hospital cleaning use pattern due to a smaller amount of product applied and the frequency that products are used. This information indicates that the product is used less frequently than originally assumed, and the agency is requiring to amend product labels to reflect the accurate use frequency of registered products.

Therefore, the agency is requiring that registrants specify on product labels that phenol and salt products may only be used by occupational handlers for a maximum of one hour per day. If the use patterns require more than one hour, then a respirator would be required (see 2 below). By reducing the number of hours that occupational handlers use phenol products in a day, the inhalation exposure will be greatly reduced as well as the risk of concern. See Appendix B for more details.

and/or

[7] EPA Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manual)

(2) *Respirator Requirement for Phenol and Salt Handlers*

If occupational handlers use the products for longer than one hour, the agency is requiring a respirator for these uses. The agency is requiringing occupational handlers to wear a NIOSH approved air-purifying half-face mask elastomeric respirator (PF 10) with any R or P filter during use. The use of this respirator will mitigate the vapor risks of concern.

The registrant provided information that PPE, including respirators, is already an industry requirement for hospital pharmacy compounding uses and mold remediation. Thus, the respirator requirement is not expected to be a burden on end users.

The agency also discussed both respirator mitigation and use frequency for phenol and salt labels with registrants, and the registrants are in agreement with implementing these options.

The EPA has recently required fit testing, training, and medical evaluations for all handlers who are required to wear respirators.[8] If a phenol and salt handler currently does not have a respirator, an additional cost will be incurred by the handler or the handler's employer. The Safety Data Sheet (SDS) for phenol already recommends the use of respirators in these circumstances, therefore this mitigation strategy should not have a major impact on users.

Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on available information, the average cost of an elastomeric half mask respirator is $35, with replacement cartridges averaging around $19.[9] The impact of the respirator requirement is likely to be substantially lower for a phenol and salt handler who is already using a respirator because the handler or handler's employer is likely to use other chemicals requiring a respirator in the production system or as part of the business (*i.e.*, the handler or employer will only incur the cost of purchasing filters for the respirator on a more frequent basis).

B. Tolerance Actions

There are two tolerance exemptions established for phenol as an inert ingredient (solvent/co-solvent) in pesticide products used on growing crops (40 CFR 180.920) and on livestock (40 CFR 180.930). At the time of the RED, there were no active registrations for those uses; therefore, the document recommended the tolerance be revoked. EPA has confirmed there is now

[8] The Revised Respirator Section of the Label Review Manual Chapter 10 is available at https://www.epa.gov/pesticide-registration/label-review-manual-chapter-10-revised-respirator-descriptions-public-comment

[9] Gempler's. 2016. Commercial-Grade Outdoor Work Gear Online Catalogue. Accessed online on August 26, 2016, at http://www.gemplers.com/respirators

an active registration for the 40 CFR 180.930 use. However, there continue to be no registrations for products containing phenol as an inert ingredient for the 40 CFR 180.920 use, and the agency is recommending in this document that the tolerance exemption for that use be revoked.

The registrants have agreed to remove food contact surface uses from their labels; therefore, a tolerance for food uses is not being proposed at this time.

C. Data Requirements

The agency does not require additional data for phenol and salt at this time.

V. NEXT STEPS AND TIMELINE

A. Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the agency is issuing the *Phenol and Salt Interim Registration Review Decision.* Except for the Endocrine Disruptor Screening Program (EDSP), the agency has made the following ID: (1) no additional data are required at this time; and (2) changes to the affected registrations or their labeling are needed at this time, as described in Section IV. A and Appendices A and B.

In this ID, the agency is making no human health or environmental safety findings associated with the EDSP screening of phenol and salt. The agency has made a "no effect" determination for the registered uses of phenol and salts under the ESA. The agency's final registration review decision for phenol and salts will be dependent upon the result of the agency's EDSP FFDCA § 408(p) determination.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the phenol and salt registrants must submit amended labels that include the label changes described in Appendix B. The revised labels and requests for amendment of registrations must be submitted to the agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Appendix A: Summary of Required Actions for Phenol and Salt

Registration Review Case#: 4074 PC Codes: 064001, 064002					
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Required Actions
All population subgroups	Residues on treated food contact surfaces	Ingestion	Chronic	Reduction in mean fetal body weight/litter	Change label language to remove food-contact surface uses
Occupational Handlers	Phenol aerosol produced from mopping use	Dermal absorption	Chronic	Reduction in mean fetal body weight/litter	Require chemical resistant glove PPE
Occupational Handlers	Vapors from general purpose cleaner	Inhalation of vapors	Short, Intermediate, Long Term	Reduction in mean fetal body weight/litter	Require PF10 respirators for remediation workers and/or limit the frequency and time of use to one hour per day

Appendix B: Required Labeling Changes for Phenol and Salt Products

Description	Required Label Language for Phenol and Salt Products	Placement on Label
Remove References to Food-Contact Surfaces	Specify that products can only be used on floors and walls in commercial dietary settings. Also, include language "Not for use on food contact surfaces."	Directions for Use
Require Glove PPE for Occupational Handlers	Occupational handlers are required to wear gloves for mopping. Glove statements must be consistent with Chapter 10 of the Label Review Manual and list the appropriate chemical resistant glove types to use.[10]	Directions for use
Require Time Limitations and/or Respirator PPE on Trigger Spray and Ready—To-Use Wipes for Occupational Handlers	"Occupational handlers must limit use to one hour per day." and/or "If occupational handler use exceeds one hour per day, handlers must wear a minimum of a PF10 NIOSH-approved elastomeric half mask respirator with organic vapor (OV) cartridges; OR a NIOSH-approved full-face respirator with OV cartridges; OR a gas mask with OV canisters; OR a powered air purifying respirator with OV cartridges."	Directions for Use
Respirator Fit Testing, Medical Qualification, and Training	"Using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134), employers must verify that any handler who uses a respirator is: • Fit-tested and fit-checked, • Trained, and • Examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional who will evaluate the ability of a worker to wear a respirator. The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as a physical exam, might be necessary. The initial evaluation must be done before respirator use begins. Handlers must be reexamined by a qualified medical practitioner if their health status or respirator style or use-conditions change. Upon request by local/state/federal/tribal enforcement personnel, employers must provide documentation demonstrating how they have complied with these requirements."	Directions for Use

[10] EPA Label Review Manual (https://www.epa.gov/pesticide-registration/label-review-manual)